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10/688,362	10/16/2003	Dongping Lin	3896-002	2296

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EXAMINER

LAYNO, CARL HERNANDZ

ART UNIT PAPER NUMBER

3762

DATE MAILED: 09/03/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/688,362

Applicant(s)

LIN ET AL.

Examiner

Carl H. Layno  
Carl H. Layno

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 16 October 2003.  
2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.  
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 31-46 is/are pending in the application.  
4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.  
5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.  
6) ☒ Claim(s) 31-37, 40 and 46 is/are rejected.  
7) ☒ Claim(s) 38, 39 and 41-45 is/are objected to.  
8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.  
10) ☒ The drawing(s) filed on 16 October 2003 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)  
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)  
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.  
4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.  
5) ☐ Notice of Informal Patent Application (PTO-152)  
6) ☐ Other: \_\_\_\_\_.

### **DETAILED ACTION**

1. Acknowledgment is made of applicant's preliminary amendment, which was received by the Office on October 16, 2003.

2. Claims 1-30 are canceled. Claims 31-46 have been added and are active.

#### ***Priority***

3. Acknowledgment is made of applicant's claim for priority as a Continuation of U.S. Application Serial No. 09/591,669, filed June 12, 2000, now U.S. Patent No. 6,658,290.

#### ***Drawings***

4. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the "wearable housing" of Claim 1 must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the

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drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. The replacement sheet(s) should be labeled "Replacement Sheet" in the page header (as per 37 CFR 1.84(c)) so as not to obstruct any portion of the drawing figures. If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

### ***Specification***

5. The disclosure is objected to because of the following informalities:

-p. 1, 1<sup>st</sup> paragraph should be updated to reflect the fact that U.S Application Serial No. 09/591,669 is now U.S. Patent No. 6,658,290.

Appropriate correction is required.

### ***Claim Objections***

6. Claim 37 is objected to because of the following informalities:

-Claim 37 depends upon a canceled claim. To overcome this objection, the Examiner recommends replacing the words "claim 5" (line 1) with the words "claim 34".

Appropriate correction is required.

### ***Claim Rejections - 35 USC § 112***

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it

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pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claims 31-33 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. Claim 31 contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Specifically, the feature of a “wearable housing” (claim 31) is neither shown in the drawings or described in the specification. In general, the Examiner could find no description of the defibrillator housing and any of the features which would make it “wearable”.

Claims 32 and 33 are also rejected since they depend from rejected base claim 31.

9. The following is a quotation of the second paragraph of 35 U.S.C. 112:

~ The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

10. Claim 32 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically, the Examiner could find no antecedent basis for the term “said cardiac arrhythmia detector (lines 1-2). To overcome this rejection, the Examiner recommends changing this term to “said cardiac rhythm detector”.

### ***Claim Rejections - 35 USC § 102***

11. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

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A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

12. Claim 31 is rejected under 35 U.S.C. 102(b) as being anticipated by Heilman et al '134.

The Heilman et al '134 patent describes a wearable portable external automatic defibrillator **10** (Fig.4) comprised of electrodes **20** and circuitry (Fig.1) including a plurality of sensors **94,48, 22** and sensing circuits **108,110,112,114** (col.8, lines 5-16). A microprocessor **116** performs the function of applicants' "cardiac rhythm detector" and "microprocessor-based controller" by detecting and recording arrhythmias (col.8, lines 17-21) while also initiating electrical therapy treatments (col.8, lines 22-37). The therapy delivery circuits comprise both pacing circuits **134** (Fig.1) and defibrillating circuits **136** (col.8, lines 49-51).

13. Claim 31 is rejected under 35 U.S.C. 102(e) as being anticipated by Owen et al '233.

The Owen et al '233 patent describes a wearable external defibrillator 10 (Fig.2) attached to electrodes 31 through a harness 4. The electrodes 31 are electrically connected to sensing circuits 56 (Fig.8), which is connected to processing block 64 which performs the function of applicant's "cardiac rhythm detector". This processing block 64 can comprise a microprocessor (col.25, line 52) and processes software capable of analyzing sensed ECGs and identifying life threatening arrhythmias (block S1202 of Fig.12). The device includes therapy delivery circuits 66, 67, 69, 70, and 71 (Fig.8).

14. Claims 34-37 and 40 are rejected under 35 U.S.C. 102(b) as being anticipated by Campbell '185-A2.

The Campbell '185-A2 European Patent describes a defibrillator (Fig.1) which can operate both automatically and semi-automatically. The defibrillator includes dual-purpose electrodes (not numbered) attached to a patient 101 and connected via signal processing circuit 102 and A/D converter 103 to microprocessors 104 and 105 (Abstract, lines 3-4). Main processor 104 performs the function of applicants' "detector circuit" and "microprocessor-based controller" since it is responsible for executing ECG analysis programs (col.5, lines 26-33) while in an ANALYZE state to determine the presence of arrhythmias and is also responsible for sending a command/message to the auxiliary processor 105 indicating selected therapy output voltages when treatment is necessary (col.6, lines 1-10). The device for the most part semi-automatically, in an advisory mode, with the user pressing an ANALYZE button and energy DELIVERY button but can also operate automatically (i.e. without pushing the ANALYZE and DELIVER buttons – see col.9, lines 8-13).

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In regard to claim 37, elements **102** and **103** perform the function of applicants' "sensor circuit".

15. Claim 46 is rejected under 35 U.S.C. 102(e) as being anticipated by Borgenicht '082.

The Borgenicht '082 patent describes an external defibrillator (Fig.2) including two electrodes **137**, a detector circuit capable of detecting ECG signals **124**, and a microprocessor based circuit (MPU) **102** capable of generating either audible or visual user prompts indicative of both the patient's condition and potential treatment therapy. The device may produce the verbal prompt "charging to deliver unsynchronized energy pulse for VF" (col.5, line 67) or colored light indicators (e.g. red for treatment using asynchronous energy, indicative of VF, or yellow for treatments using synchronous energy [AF}). See col.6, lines 19-26.

***Allowable Subject Matter***

16. Claims 38, 39, and 41-45 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

17. As allowable subject matter has been indicated, applicant's reply must either comply with all formal requirements or specifically traverse each requirement not complied with. See 37 CFR 1.111(b) and MPEP § 707.07(a). Specifically, **corrected formal drawings are required.**



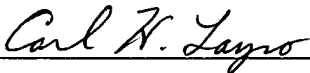
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***Conclusion***

18. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carl H. Layno whose telephone number is (703) 308-3694. The examiner can normally be reached on Monday thru Thursday from 9 AM to 6 PM and every other Friday between 9AM and 5PM. A voice mail or E-mail message ([carl.layno@uspto.gov](mailto:carl.layno@uspto.gov)) may be left if desired.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes, can be reached on (703) 308-5181. All faxed correspondence should be sent to the Office's new Official FAX number (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to Legal Instruments Examiner (LIE) Brenda Webb whose telephone number is (703) 305-7520.



CARL LAYNO  
PRIMARY EXAMINER

CHL  
9/1/2004